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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,139	05/04/2006	Daniel Martin	10139/06302	2560
76960	7590	02/09/2011		
Fay Kaplun & Marcin, LLP 150 Broadway, suite 702 New York, NY 10038			EXAMINER RAMANA, ANURADHA	
			ART UNIT 3775	PAPER NUMBER
			MAIL DATE 02/09/2011	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/529,139

Applicant(s)

MARTIN, DANIEL

Examiner

Anu Ramana

Art Unit

3775

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The Examiner is withdrawing the action mailed in error on August 6, 2010. The Examiner sincerely apologizes for any inconvenience caused to the Applicant by this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 53, the recitation "at least a portion with a conical shape" seeks to introduce new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 50, the recitation "wherein at least two of the transverse holes at least partially intersect one another" renders the claim vague and indefinite since it is unclear what structure is being claimed by the Applicant. It appears that Applicant is trying to claim that the "hole axes intersect one another."

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34-48, 50-51, and 53-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brumback et al. (US 6120504) in view of Huebner et al. (US 5472444).

Brumback et al. disclose an intramedullary nail 10 having four transverse holes (22, 22, 23, 23) grouped at the distal end of the nail (Figs. 1, 1a and 8, col. 2, lines 31-67, col. 3, lines 1-11 and col. 6, lines 9-16). Brumback et al. disclose two of the holes to be at an angle of anteversion between 10 degrees and 35 degrees, in applicant's claimed range of between 0 degrees and 90 degrees. Brumback et al. also disclose different anteversion angles for other applications.

Regarding the distance of the holes from the tip of the intramedullary nail, Huebner et al. teach a distal tip portion extending distally beyond a distal hole by a distance of about 20 to 50% of the length of a nail for securement of the nail to a humeral or bone shaft while reducing stress concentrations (col. 3, lines 15-18 and col. 4, lines 30-33).

Therefore, it would have been obvious to one of ordinary skill in the art to extend the tip of the nail beyond hole 22 by about 20 to 50% of the length of the nail of Brumback et al., as taught by Huebner et al., for fixation in a bone shaft with reduction of stress concentrations.

Although the combination of Brumback et al. and Huebner et al. do not relate the distance the tip of the nail extends beyond the axis of hole 22 to the diameter of hole 22, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have optimized the distance the tip of the nail extends beyond hole 22 or the axis of hole 22 by a distance $\leq 25d$, since it has been held that where the

general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. It is the Examiner's position that Applicant is relating the distance the tip of the nail extends beyond the distal transverse hole to the diameter of the hole rather than the length of the nail.

Regarding claims 36-43, 50 and 51, Brumback et al. also disclose different anteversion angles for other applications. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have selected an angle in the claimed ranges, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 53, Huebner et al. disclose holes having a partial conical shape to prevent rotation of screws within the holes.

Therefore, it would have been recognized by one of ordinary skill in the art at the time the invention was made that applying the known technique of providing a hole with a partial conical shape, as taught by Huebner et al., in the Brumback et al. nail would have yielded predictable results, i.e., improved fixation of the nail to the bone shaft.

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brumback et al. (US 6120504) and Huebner et al. (US 5472444) further in view of Frigg et al. (US 5041115).

The combination of Brumback et al. and Huebner et al. disclose all elements of the claimed invention except for at least five distal transverse bores or holes.

Frigg et al. teach varying the number of holes for locking screws based on the proposed use and length of the nail (Fig. 1, col. 4, lines 59-68 and col. 5, lines 1-2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the number of distal transverse holes, as taught by Frigg et al., in the nail of the combination of Brumback et al. and Huebner et al., depending on the proposed use and length of the nail.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brumback et al. (US 6120504) and Huebner et al. (US 5472444) further in view of Perry (US 5766174).

The combination of Brumback et al. and Huebner et al. disclose all elements of the claimed invention except for threaded transverse holes.

It is well known in the art to provide threaded transverse holes for engagement with screws, as evidenced by Perry (Fig. 3).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided threaded transverse holes, as taught by Perry, in the nail of the combination of Brumback et al. and Huebner et al., for positive engagement of the fixation member, namely a screw, with the nail.

Response to Arguments

Applicant's arguments have been fully considered but are not persuasive for the following reasons.

Regarding the rejection of claim 50 under 35 USC 112 second paragraph, it is noted that the claim is vague and indefinite since it is unclear what structural relationship is being claimed. Applicant's arguments "because of the three-dimensional aspect of the transverse holes, it is possible for a partial intersection in which the axes of the holes never intersect" does not clarify the ambiguity. What does Applicant mean by "partial intersection in which the axes of the holes never intersect?"

Regarding the rejection of claim 53 under 35 USC 112 first paragraph, it is noted that Applicant's disclosure, as originally filed, states "a portion of one or more screw holes may be substantially conical in geometry." However, claim 53 recites "at least a portion with a conical shape" which implies that the entire hole may be conical in shape, not supported by Applicant's disclosure, as originally filed.

Regarding the rejections under 35 USC 103(a), it is noted that Huebner et al. clearly teach optimizing the distance between a distal hole and the distal tip of an intramedullary nail. It is the Examiner's position that the prior art clearly suggests

optimizing this distance for reduction of stress concentrations. Whether the distance is a function of the total nail length or a function of hole diameter is a mathematical expression/manipulation of the prior art teaching of optimizing the distance between the distal end of the nail and the distal-most hole for reducing stress concentrations.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached at (571) 272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
February 4, 2011

/Anu Ramana/
Primary Examiner, Art Unit 3775